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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,365	08/03/2001	Michel Andre Crepeau	VIT-2 (5500*86)	6748
23416	7590	11/19/2003	EXAMINER	
CONNOLLY BOVE LODGE & HUTZ, LLP			OH, SIMON J	
P O BOX 2207			ART UNIT	
WILMINGTON, DE 19899			PAPER NUMBER	

1615

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/920,365	CREPEAU, MICHEL ANDRE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, and request for continued examination, all received on 17 October 2003.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Kardys in view of Tipton *et al.* is rendered moot with the cancellation of those claims.

Claims 10-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kardys in view of Tipton *et al.*

Kardys teaches a high potency vitamin formulation which easily disperses in water. This formulation includes at least one oil-soluble vitamin selected vitamin A, vitamin D<sub>2</sub>, vitamin D<sub>3</sub>, vitamin E, or combinations thereof (See Column 2, Lines 15-53). Another principal component is an emulsifier or dispersing agent, described as a polyoxyethylene derivative of certain high molecular weight fatty acid esters, with the sorbitan fatty acid esters cited as a specific example (See Column 1, Lines 20-41 and Column 2, Lines 53-68). The third principal component of this formulation is chosen from the group comprising polyethylene glycol 400 monooleate, decaglycerol dioleate, or decaglycerol trioleate (See Column 3, Lines 1-12). Both the second

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and third principal components of this composition fall under the category of what the applicant describes as non-ionic surfactants. In addition, Kardys teaches that the oil soluble vitamins may also be blended with corn oil or other mineral or vegetable oil (See Column 3, Lines 22-48; and Examples II, III, IV, and X). Example X in Kardys also shows a formulation that includes ethanol or alternatively, normal propanol, in its formulation (See Column 8, Lines 19-32), both of which fall under the description of the C<sub>2</sub> to C<sub>6</sub> mono-hydroxy alcohol described in Claim 1. Ethoxyquin is also included in the formulation as a stabilizer against oxidation and polymerization (See Examples I-X; and Column 4, Lines 26-27). Kardys also teaches that this formulation can disperse rapidly in water, usually in less than a minute, within a matter of seconds, to give clear and stable vitamin solutions of high potency (See Column 2, Lines 3-13; Column 3, Lines 13-38; and Examples I and X).

Kardys is deficient in that it does not teach the inclusion of either a C<sub>1</sub> to C<sub>6</sub> alkyl lactate in the vitamin composition.

The Tipton *et al.* patent teaches high viscosity liquid compositions useful for the delivery of biologically active substances (See Column 1, Lines 4-5; and Column 6, Lines 50-52). This composition can be administered by a variety of means, including topically, orally, or parenterally (See Column 10, Lines 39-49). Vitamins, such as vitamin E, are included among the possible biologically active substances useful for this composition (See Column 6, Lines 62-63; and Column 8, Line 15). Ingredients that may comprise this composition include oils and fats such as vegetable oil and corn oil (See Column 9, Lines 49-54); non-ionic surfactants, preferably polyoxyethylene sorbitan fatty acid esters (See Column 11, Lines 40-54); co-surfactants including ethyl alcohol, propylene glycol, and non-ionic surfactants such as

polyethylene glycol (See Column 11, Line 60 to Column 12, Line 12). It is preferred that a solvent also be included in the formulation, as a viscosity-decreasing agent. The presence of such a solvent allows for easier flow and easier formulation as an emulsion (See Column 5, Lines 50-57; and Column 10, Lines 50-52). Suitable solvents include ethanol and ethyl lactate (See Column 10, Lines 15-16).

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kardys in view of Tipton *et al.* into the objects of the instant application. One of ordinary skill would seek to resolve the deficiency of the Kardys patent by adding ethyl lactate into the formulation, being motivated to do so as way of controlling the viscosity of the composition, as well as producing a composition that can be more easily be formulated as an emulsion or dispersion, as disclosed by the Tipton *et al.* patent. It is the position of the examiner that it is within the purview of one of ordinary skill in the art at the time the instantly-claimed invention was made to determine, through routine experimentation, features of the invention embodied in claim limitations directed to 1) weight ratios of an alkyl lactate to a mono-hydroxy alcohol, 2) viscosity of the composition, and 3) dispersion rates of specific proportions of composition to water. Furthermore, as the compositions arising from the collective disclosure of the prior art read on those compositions disclosed in the instant application, it is the position of the examiner that properties such as viscosity and dispersion rates are inherent to the disclosure of the prior art. Regarding Claims 17-20, it is the position of the examiner that such specific embodiments of components in the composition are not considered critical to the function of the instantly claimed invention. The examiner shifts the burden onto the applicant to clearly show the criticality of these features or otherwise show that

the incorporation of such features would be outside the knowledge of one of ordinary skill in the art at the time the instantly claimed invention was made.

Thus, the instantly claimed invention as a whole is *prima facie* obvious.

### ***Response to Arguments***

Applicant's arguments filed 17 October 2003 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding the applicant's arguments against Kardys, the examiner emphasizes that in the present rejection, so long as an overlap exists between the instantly claimed ranges and the ranges disclosed by the prior art, obviousness of these features is established.

Regarding the applicant's arguments against Tipton *et al.*, it is not necessary that the art recognize each and every function of a component to be included within a composition, only that a particular component is known as being useful in a particular composition.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjj

  
THURMAN K. PAGE  
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